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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,936	12/21/2001	Roger Briesewitz	STAN066DIV	8489

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025 934

Applicant(s)

Briesnitz et al

Examiner

Hafj

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/21/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 16-44 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 16-44 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 7.106 4/18/02
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The preliminary amendment of 12/21/01 canceled claims 1-15 and 45-47.

Claims examined on the merits are 16-44 which are all claims in the application.

5

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bifunctional molecule of less than about 5000 daltons, does not reasonably provide enablement for a larger bifunctional molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

20 In view of the specification (page 8, line 17), the bifunctional molecule should not exceed 5000 daltons, and it does not appear a larger molecule would function in the methods of the claimed invention as the molecule of less than 5000 daltons.

Claim Rejections - 35 USC § 112

25 The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

30

Claims 16-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claims 16, 23 and 38, requiring the ligand and drug to be optionally joined by a linking group makes the claim unclear and confusing as to patentably limiting metes and bounds. If a linking group is not required, the group should be omitted from the claims where optional, and required in a dependent claim where the linking group is required.

10 In claims 16, 23, 29 and 33 requiring enhanced properties as compared with a control is uncertain as to meaning and scope since the enhanced property cannot be determined without knowing the specific control.

Claims 23 and 29 are confusing by after "whereby" requiring the
15 bifunctional molecule to bind a target of the drug in addition to binding the presenter protein since a target for the drug different from the presenter protein has not been previously required. Additionally, it is unclear how the bifunctional molecule can bind to a target of the drug in addition to the presenter protein since the ligand of the molecule is
20 specific only to the presenter protein, and there is nothing contained by the bifunctional molecule than will bind a target for the drug that is not the presenter protein. Additionally, in the penultimate line of these claims, reciting "presenter protein target binding interactions" is confusing since the claim requires the presenter protein to bind to the
25 ligand of the bifunctional molecule and not to a target.

In claim 33, requiring the binary complex produced to exhibit enhanced specificity for a target of the drug moiety of the bifunctional molecule is confusing since a target for the drug moiety has not been previously required, and the complex contains nothing that is capable of binding to a target for the drug moiety.

Claim 35 is confusing and unclear as to what constitutes the target of the drug and how the target and presenter protein differ, and how producing the binary complex in the second cell enhances selectivity of a drug for a target in the first cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chakraborty et al (AW-1) or Crabtree et al (AX-1) in

view of Young et al (WO 98/47916) (AB-1) or Lussow et al (AJ-1) or Pouletty et al (WO 95/10302) (AK-1) or Krammer et al (AZ-1).

The claims are drawn to methods of producing a binary complex or a tripartite complex in a host, or administering a drug to a host by administering to the host a bifunctional molecule containing a drug moiety and a presenter protein ligand, or a method of enhancing selectivity of a drug for a target in a first cell as compared to a second cell by contacting the first and second cells with the bifunctional molecule to form a binary complex in the second cell.

Chakraborty et al and Crabtree et al disclose a ligand such as FK506 that binds to peptidyl prolyl isomerase (FKBP).

Young et al, Lussow et al, Pouletty et al and Krammer et al disclose producing conjugates where one part is a drug and the other part has affinity for a cell or part thereof to target the drug to a specific location.

It would have been obvious to form a conjugate of a drug and the ligand of FKBP when desiring to target the drug to FKBP as suggested by Young et al, Lussow et al, Pouletty et al or Krammer et al.

Administering the conjugate to a host would have been an obvious use of the conjugate, and administering the conjugate to a host would have inherently formed binary and tripartite complexes and provided a drug to the host. Additionally, administering the conjugate to a host would have inherently resulted in selectively as required by claims 35-37.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on

Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
3/20/03